DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94350.4

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER
NWE-27-03W

VIA FEDERAL EXPRESS

September 24, 2003

William Barnstead
President
Consolidated Machine Corporation
76 Ashford Street
Boston, MA 02134

Dear Mr. Barnstead:

An inspection of your facility located at 76 Ashford Street, Boston, MA was initiated by an investigational team from the Food and Drug Administration (FDA) on May 29, 2003 and completed on May 30, 2003. This inspection verified that your firm manufactures steam sterilizers. These products are medical devices, as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection confirmed that in 1994 your firm introduced the Mark V microprocessor that is marketed as an attachment to all of your approximately fourteen steam sterilizers. This microprocessor is software driven and controls the time and temperature of the sterilization cycles. This microprocessor addition constitutes a significant change in design technology, which could affect the safety or effectiveness of the device. This modification requires the submission of a premarket notification (510(k)) to FDA as described under Title 21 Code of Federal Regulations (21 CFR) part 807.81(a)(3)(i).

Your failure to submit a premarket notification under Section 510(k) of the Act causes your Steam Sterilizers equipped with the Mark V microprocessor to be misbranded under Section 502(o) of the Act. Moreover, in the absence of valid marketing clearance (i.e., 510(k) clearance) from FDA, this device is automatically rendered a Class III device under Section 513(f) of the Act. No Class III device may be introduced into interstate commerce unless you first obtain from

FDA either premarket approval (PMA) pursuant to Section 515(a) of the Act or an approved investigational device exemption (IDE) pursuant to Section 520(g) of the Act. Since you hold neither an approved PMA nor an approved IDE for this device, the Steam Sterilizers equipped with the Mark V microprocessor are also adulterated under Section 501(f)(1)(B) of the Act.

The above-stated inspection also revealed that your steam sterilizers equipped with the Mark V microprocessor are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to validate a process where the results of the process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, your firm has not validated the microprocessor used with your steam sterilizers.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all applicable regulations and provisions of the Act. Federal agencies are advised of the issuance of all Warning Letters about drugs and medical devices, so that they may take this information into account when considering the award of contracts. Additionally, pending export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

We acknowledge your letter dated June 6, 2003 which was in response to the FDA 483. We have the following comments. Your written response to this Warning Letter should incorporate the corrective actions required below.

Please describe how your device master record meets all the requirements set forth in 21 CFR Part 820.181, specifically, the quality assurance procedures including all of your acceptance criteria.

Your complaint procedure also needs to adhere to all the requirements of 21 CFR Part 820.198. For example, each complaint needs to be reviewed to assure it is not reportable under the medical device reporting (MDR) requirements, (21 CFR 803).

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

Gail F. Costello
District Director
New England District Office